

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A preparation containing active and/or auxiliary substance(s), for the time- and/or dose-controllable release of said substances, comprising a laminate made up of at least a carrier layer (1) and a matrix layer (2), said laminate being in rolled or folded shape, wherein

- a) the matrix layer (2) has a longitudinal extension, contains at least one active or auxiliary substance, and is continuous at least in sections thereof,
- b) at least one of the parameters of width and concentration of the active and/or auxiliary substance of this layer is not constant in relation to said longitudinal extension,
- c) said carrier layer (1) is continuous and possesses a lower moisture permeability than the matrix layer (2), and

wherein at least one of said layers (1, 2) comprises a liquid-soluble adhesive which dissolves when the preparation is exposed to a body fluid.

2. (Previously Presented) The preparation according to Claim 1, wherein in the longitudinal direction of the carrier layer (1), active substance-containing regions of the matrix layer (2) alternate at distances with active substance-free regions of the carrier layer (1).

3. (Previously Presented) The preparation according to Claim 1, that further comprises at least one continuous and substantially moisture-impermeable layer.

4. (Previously Presented) The preparation according to Claim 3, wherein the substantially moisture-impermeable layer contains one or more active substances and/or auxiliary substances.

5. (Currently Amended) The preparation according to Claim 1, wherein the matrix layer (2) of the laminate is soluble or erodible in body fluid, and the carrier layer (1) is less readily soluble or more difficult to erode, or is ~~even-insoluble or erodible~~ not erodible.

6. (Previously Presented) The preparation according to Claim 1, wherein the concentration of the active substance or of the active substances varies in respect to the longitudinal extension of the active substance-containing layer(s), or is in the form of a concentration gradient or an otherwise variable concentration profile.

7. (Previously Presented) The preparation according to Claim 1, wherein at least one layer is a pressure-sensitive adhesive layer.

8. (Previously Presented) The preparation according to Claim 1, wherein the laminate is spirally rolled up, and said matrix layer (2) forms an outer layer of the spirally rolled-up laminate and contains active and/or auxiliary substances.

9. (Previously Presented) The preparation according to Claim 1, wherein the laminate is spirally rolled up, and said matrix layer (2) forms an inner layer of the spirally rolled-up laminate and contains active and/or auxiliary substances.

10. (Previously Presented) The preparation according to Claim 1, wherein one layer has regions with active and/or auxiliary substances, which regions differ in terms of their solubility, adhesive power or erosion properties.

11. (Previously Presented) The preparation according to Claim 1, configured in form of a winding, that comprises a winding core which comprises a material which is soluble in body fluid.

12. (Previously Presented) The preparation according to Claim 1, wherein in the center of the winding there is formed a tube recess of at least 0.5 mm in diameter.

13. (Previously Presented) The preparation according to Claim 1, wherein the preparation effects a linear release of active substance.

14. (Previously Presented) The preparation according to Claim 1, wherein the preparation effects the release of an initial dose.

15. (Previously Presented) The preparation according to Claim 1, wherein those sides of a spirally rolled-up or folded preparation which correspond to longitudinal sides of the respective layers are provided with additional cover layers, said cover layers preferably containing substantially moisture-impermeable materials.

16. (Previously Presented) The preparation according to Claim 1, wherein the preparation is embedded in a substrate (5) which comprises a substance that is soluble in an acidic or basic environment.

17. (Previously Presented) A method for the controlled release of an active and/or auxiliary substance in the anal or vaginal region, or as an implant, comprising:
administering the preparation according to claim 1 to said vaginal or anal region; or
implanting said preparation into the body.

18. (Previously Presented) A method for releasing active and/or auxiliary substances in the gastrointestinal tract, in the small intestine or in the large intestine, comprising:
administering the preparation according to claim 1 by oral application.

19. (Previously Presented) A method for releasing an active and/or auxiliary substance in the region of the gastric juice, comprising:

administering the preparation according to claim 1 by oral application.

20. (Previously Presented) A process of manufacturing the preparation according to Claim 1, comprising:

- providing a carrier layer (1),
- coating said carrier layer (1) with at least one matrix layer (2) containing active and/or auxiliary substance, thus forming a laminate having a longitudinal extension,
- drying of the laminate,
- applying along the longitudinal extension of the laminate a thickness and/or width profile which can be modulated as required for achieving predeterminable release kinetics,
- forming an application form from the preparation by rolling or folding, and
- final packaging, wherein at least one of said layers (1, 2) comprises a liquid-soluble adhesive which dissolves when the preparation is exposed to a body fluid.

21. (Previously Presented) The process according to Claim 20, wherein to achieve a desired release schedule following administration parts of the matrix layer (2) are removed or added in the longitudinal extension of the laminate.

22. (Previously Presented) The process according to Claim 20, wherein further active layers (3, 4) are laminated to the laminate.

23. (Previously Presented) The process according to Claim 20, wherein the preparation is embedded in a substrate (5).

24. (Previously Presented) The preparation of claim 1, configured in form of a winding, that comprises a winding core which comprises a material which is insoluble in body fluid.

25. (New) The preparation of claim 1, in which the geometry and/or concentration of the active substance layer varies in the longitudinal direction of the matrix such that the release of at least one active substance is temporally in a pulsatile manner, in a manner in which the release is repeatedly modulated to increase and then decrease, or in a manner that is a rise in the release followed by a fall in the release.